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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/982,853	10/22/2001	Avraham Shekalim	2472/2	7675	
75	90 02/04/2003				
DR. MARK FRIEDMAN LTD.		EXAMINER			
C/o Bill Polkinghom Discovery Dispatch			KONTOS, LINA R		
9003 Florin Wa Upper Marlboro			ART UNIT	PAPER NUMBER	
••	•		3763		
			DATE MAILED: 02/04/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

mfg ina @ friedpat.com

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=		Application No.	Applicant(s)				
Office Action Summary		09/982,853	SHEKALIM, AVRAHAM				
		Examiner	Art Unit				
	The Man 1910 Date	Lina Kontos	3763				
Period for	The MAILING DATE of this communication app Reply	ears on the cover sheet with the c	orrespondence address				
I HE M Extensi after SI - If the po - If NO p - Failure - Any rep	PRTENED STATUTORY PERIOD FOR REPLY AILING DATE OF THIS COMMUNICATION. ions of time may be available under the provisions of 37 CFR 1.13 IX (6) MONTHS from the mailing date of this communication. eriod for reply specified above is less than thirty (30) days, a reply recid for reply is specified above, the maximum statutory period w to reply within the set or extended period for reply will, by statute, ply received by the Office later than three months after the mailing patent term adjustment. See 37 CFR 1.704(b).	6(a). In no event, however, may a reply be tim within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from Cause the application to become ABANDONE	rely filed  s will be considered timely. the mailing date of this communication.				
1)	Responsive to communication(s) filed on						
		s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims							
4)⊠ Claim(s) <u>1-21</u> is/are pending in the application.							
ł	4a) Of the above claim(s) is/are withdrawn from consideration.						
1	5) Claim(s) is/are allowed.						
6)⊠ C	6)⊠ Claim(s) <u>1,2,6,7 and 10-16</u> is/are rejected.						
7)⊠ C	7)⊠ Claim(s) <u>3-5,8,9,17-21</u> is/are objected to.						
8) C	Claim(s) are subject to restriction and/or n Papers	election requirement.					
9)⊠ Th	ne specification is objected to by the Examiner.						
10)⊠ Th	ne drawing(s) filed on <u>10/22/2001</u> is/are: a)□ a	ccepted or b) Objected to by the	Examiner.				
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. Se	e 37 CFR 1.85(a).				
	ne proposed drawing correction filed on		ed by the Examiner.				
	If approved, corrected drawings are required in repl	<u>-</u>					
	ne oath or declaration is objected to by the Exa	miner.					
	der 35 U.S.C. §§ 119 and 120						
41	13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
]]	a) All b) Some * c) None of:						
1	1. Certified copies of the priority documents have been received.						
1	Certified copies of the priority documents						
1	<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
1.1	knowledgment is made of a claim for domestic	•					
` \ _a) [	The translation of the foreign language provknowledgment is made of a claim for domestic	isional application has been rece	ived.				
Attachment(s)							
2) Notice o	of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) tion Disclosure Statement(s) (PTO-1449) Paper No(s) 2.		PTO-413) Paper No(s) atent Application (PTO-152)				
U.S. Patent and Trade PTO-326 (Rev. (		on Summary	Part of Paper No. 1				

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### **Drawings**

1.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "connection extensions 38", "housing pieces 40" and "end region 72". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

#### Specification

2.

The abstract of the disclosure is objected to as it contains a typographical error in the first line: the phrase "an accurate" is unnecessarily repeated. Correction is required. See MPEP § 608.01(b).

*3*.

The disclosure is objected to because of the following informalities:

Page 18, lines 18-19 - "Figure 4" should be changed to -- Figure 6--

Page 18, line 21 - "Figure 6" should be changed to -- Figure 7--

Appropriate correction is required.

# Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4.

Claims 1,2,6,7 are rejected under 35 U.S.C. 102(b) as being anticipated by Singh et al.

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Singh et al. teaches an infiltration indicator for an infusion system comprising a long rigid duct (column 2, line 20) with holes (column 2, line 22) which joins to the tubing of the infusion system (column 2, lines 37-39). Surround the duct is a closely fitting elastomeric tube (column 2, lines 24-25). When infiltration occurs, fluid flowing through the duct seeps out the holes, expanding the elastomeric tube (column 2, lines 30-32), and changing the status of electrical contacts, thus triggering an alarm (column 2, lines 57-59 and column 3, lines 16-23).

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

*5*.

Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. in view of Atkins et al.

Signh et al., as described above, teaches a infiltration indicator for use with an infusion pump system.

Atkins teaches a method for detecting fluid infiltration during the administration of intravenous fluids comprising sensors and an alarm system wherein the entirety of the system can be powered by battery (column 5, line 50). Tissue infiltration is indicated by the sounding of an alarm, or a visible light (column 5, lines 31-34).

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It would have been obvious to one skilled in the art of the time of the invention to make the system powered by battery in order to allow to system when in use with an infusion pump to be mobile. Furthermore, it would have been obvious for the alarm of Singh's invention to provide either a visual or audible signal to alert to patient or attending staff to an instance of infiltration.

6.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Signh in view of Olson.

Signh et al., as described above, teaches a infiltration indicator for use with an infusion pump system. Additionally, he further discloses that when the pressure exceeds a predetermined level, that elastomeric tubing is inflated, causing an alarm to be triggered. However, the amount of pressure that causes the elastomeric tubing to expand is variable dependent on the material and thickness of the tubing used.

Olson teaches an infusion pump apparatus comprising a fluid storage bottle (column 2, line 61), a flow control valve (column 3, line 50) and an indicator light to warn of overpressure (column 5-6, lines 68-1).

It would have been obvious to one skilled in the art at the time of the invention to incorporate to incorporate Singh's invention into an infusion pump system employing the use of a flow control valve in order to prevent backflow.

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# Allowable Subject Matter

7. Claims 3-5,8,9,17-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lina Kontos whose telephone number is (703) 306-4207. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

LRK January 29, 2003

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700